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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/040,242 | 11/09/2001 | Michelle Lu | 680.0043USU | 9256 |
| 7590 | 02/11/2005 | | | EXAMINER |
| Charles N.J. Ruggiero, Esq. Ohlandt, Greeley, Ruggiero & Perle, L.L.P. 10th Floor One Landmark Square Stamford, CT 06901-2682 | | | GHALI, ISIS A D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| DATE MAILED: 02/11/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/040,242 | LU ET AL. | |
| | Examiner Isis Ghali | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 September 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11,12 and 19-24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10,13-18 and 25-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE under 1.114, filed 09/07/2004.

Claims 1-29 are pending in the application, claims 11, 12, 19-24 are withdrawn from consideration as being directed to non-elected inventions.

Claims 1-10, 13-18, and 25-29 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/07/2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10, 13-18 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for homogenized seed cell broth, does not reasonably provide enablement for cultured substantially undifferentiated plant seed cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the instant claimed invention is composition comprising cultured substantially undifferentiated plant seed cells and pharmaceutically or cosmetically acceptable vehicles; and method of improving the aesthetic appearance of skin comprising topically applying a composition having cultured substantially undifferentiated plant seed cells and pharmaceutically or cosmetically acceptable vehicles.

The breadth of the claims: The claims are broad. The claims encompass a wide class of cultured plant seed cells. The claims language includes even the whole seed because the cells are not processed. In page 5, second paragraph of the specification, applicants teach culturing whole seeds, or portions thereof.

The state of the prior art: The state of the art does not recognize the incorporation of the cultured neem seed cells in a pharmaceutical or cosmetic composition and method of its use to improve the aesthetic appearance of the skin, but the art recognized the use of the cultured plant seed cells, as in US 2002/0071878, and plant extract in pharmaceutical composition to treat dermatological disorders, as in WO 00/64472, abstract, page 11, lines 3-10, 20-25; page 12, lines 1-15; page 25, lines 26-30. The state of the art does not recognize the use of neem seed cultured cells for cosmetics, but recognized the use of cultured neem seeds as an insecticide.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on the incorporation of the culture comprising plant seed cells into a cosmetic or pharmaceutical composition. The specification enabled the homogenized cultured seed cell in the broth medium. No guidance from the present disclosure regarding the condition in which the culture contain whole seeds, without homogenization, how this could be incorporated in the composition, some seeds are relatively large in size. Claim 10 recites the composition is in a product selected from aerosol spray, cream, dispersion, foam, gel, lotion, mousse, ointment, powder, patch, pomade, solution, pump spray, stick and towelette, and it is

not clear from the specification how the undifferentiated plant seed cells will be incorporated as a whole seed in any of the above products.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to using cultured undifferentiated plant seed cells in their culture in a composition, without further processing, wherein the seeds could be whole seeds, makes practicing the claimed invention unpredictable in the terms of using undifferentiated seed cells.

The presence or absence of working examples: The specification discloses culturing whole seeds or portions thereof, page 5, and incorporation of the homogenized culture media as a whole into the composition, page 7. No working examples to show how the culture media incorporating the seeds or seed cells would be admixed into the composition, without homogenization, to provide a cosmetic or pharmaceutical composition in the various products claimed in claim 10.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant composition without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

4. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving the aesthetic appearance of the skin, page 10, last paragraph, does not reasonably provide enablement for preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing

hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of *In re Wands* factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, the working examples, and the amount of experimentation necessary. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

The nature of the invention: The rejected claims are drawn to the methods of improving the aesthetic appearance of the skin, i.e. the skin is already compromised, wherein the improvements include preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation with the administration of the instant composition. The nature of the invention is extremely complex in that it encompasses multiple complex skin conditions having unrelated manifestations and subsequently prevented by administering the instant composition comprising substantially undifferentiated plant seed cells.

The breadth of the claims: The complex nature of the claims is exacerbated by the breadth of the claims. The claim encompasses prevention of complex conditions that may have potential causes other than those disclosed in the specification. This may or may not be addressed by the administration of the claimed composition. Moreover,

the specification is directed to skin conditions caused by aging, see page 10 of the specification. However, numerous other skin conditions, such as discoloration, signs of fatigue and skin barrier repair, are encompassed by the instant claims

The state of the art: The state of the art does not recognize the administration of compositions to prevent the skin conditions as required in the instant claims. The state of the art recognizes the treatment of the symptoms of these skin conditions but not their prevention or cure, WO 00/64472.

The guidance of the specification: The guidance given by the specification on how to prevent the skin conditions is absent. Guidance for improving the aesthetic appearance of skin is provided, no evidence that these conditions are prevented is provided.

The predictability of the art: The lack of significant guidance from the specification or prior art with regard to completely preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation with the administration of the instant composition comprising undifferentiated plant seed cells makes practicing the claimed invention unpredictable in terms of the prevention of these conditions.

The presence or absence of working examples: The specification discloses improving the aesthetic appearance of the skin, no working examples to show preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of

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glycosaminoglycans, or preventing cellulite formation by administrating the instant composition.

The amount of experimentation necessary: The art demonstrates treatment of skin aging symptoms, but does not teach prevention of these conditions. Therefore, the practitioner would turn to trial and error experimentation to make/use the instant compositions for preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 8-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0071878 ('878).

US '878 disclosed a topical composition comprising cultured seed cells obtained from cucumber and carrot that used in cosmetic and dermatological compositions

(abstract; page 3, 0029-0031, page 4, table 2; page 5, 0038, 0039; page 10, 0137; page 11, 0143, 0144; page 17, claim 10). The compositions is in the form of gel, cream and comprises acceptable vehicle and selected from polyethylene glycol, oils, silicone oil, or fatty acids (page 10-11, 0137). The composition used to treat skin disorders such as hirsutism, reduction of nail growth, hair treatment, inhibition of scar formation (page 18, claim 22).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-7, and 14-18, 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '878 in view of WO 00/64472 ('472).

The teachings of US '878 are discussed above, however the reference does not teach the amount of the plant seed cells in the composition as claimed in claims 2-5, 7, 15 and 16, the specific plants used in the composition as claimed in claims 6, 14, 25-29, and the specific skin conditions treated by the composition.

WO '472 teaches a method and composition for treating dermatological conditions using fruit extract, with the extract from pomegranate is preferred (abstract). The composition used to treat age spots, reduced skin moisture, deepening of skin lines, blemished skin and impetigo (page 11, lines 7-10). The amount of the fruit extract in the composition ranges from 0.1 to 20 % (page 11 lines 15-16). The extract can be from the seed (page 11, line 24). The composition comprises a vehicle as oils and is in the form of gel or cream (page 12, lines 1-15, page 25, lines 26-30).

According to the intended use and the site of application, one having ordinary skill in the art would manipulate the amount of the cultured seed cells in the composition in order to achieve a beneficial effect, and the claimed amounts do not impart patentability to a composition comprising undifferentiated plant seed cells, absent evidence to the contrary. Also selection of specific seeds is within the skill in the art depending on the specific condition.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition comprising cultured plant seed cells in a topical composition to treat skin disorders as disclosed by US '878, and to select the

amount of the cultured seed to be incorporated in the composition and the specific plant seeds depending on the treated condition as disclosed by WO '472, motivated by the teaching of WO '472 that the fruit extracts manage dermatological conditions related to aging, with reasonable expectation of having a topical composition that provides the cultured plant seed cells to the skin nails or hair at the desired amount to a particular location with disorder and in need for the such a treatment with success.

Response to Arguments

10. Applicant's arguments filed 09/07/2004 have been fully considered but they are not persuasive.

Applicants traverse the rejection of claims 1-10, 13-18, and 25-29 as being unenabling by arguing that the claims do not require the whole seed and do not preclude their presence and no reason to be precluded from topical composition that can contain particulates, such as talc and silica.

In response to applicants' argument, the examiner position is that the plants seeds have variable sizes that can be as small as sesame seed or as huge as coconut seed, and the claims are broad enough to include all the plant seeds that are huge compared by the talc particulates. The claims do not recite the homogenized culture as disclosed by the present specification. Further applicants disclosed the administration of the composition in the form of spray, and using coarse particulates cannot be sprayed from an aerosol unless it is homogenized.

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Applicants traverse the U.S.C.112 first paragraph rejection of claims 17 and 18 by arguing that the preventing and treating are not mutually exclusive.

The examiner's position is that the specification does not enable the prevention and treatment or improving of each and single condition claimed in claims 17 and 18. One skilled in the art would be burden with trial and error experimentation to prevent and treat all the claimed conditions, for instant what prevent skin wrinkles caused by UV not necessary treat skin conditions related to estrogen imbalance. Furthermore, one cannot predict the skin disorders in order to prevent them before they become manifest.

Applicants traverse the rejection of claims 1, 8-10 and 13 as being anticipated by US '878, and the rejection of claims 2-6, 14-18, 25-29 as being unpatentable over US '878 in view of WO '472 by arguing that the reference disclosed dormant cells that include both differentiated and undifferentiated cells, and not equivalent to undifferentiated.

In response to that applicants' argument, the examiner is pointing to the claim language "substantially" that permits both differentiated and undifferentiated cells. The reference disclosed that some differentiation may occur during dormancy, and that reads on the present claims' language.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615
IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER